Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0689262	03/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dallas County Medical Center	201 Clifton Street, Fordyce, AR	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the CMS-209 forms, review of proficiency test attestations for 2022 and 2023, and interviews with laboratory staff, proficiency test samples were not tested by all personnel who routinely perform patient testing. Survey findings include: A. The CMS-209 forms signed 3/27/2023 included sixteen testing personnel (listed as Employees #2 through #17). B. A review of proficiency test attestations for 2022 through 2023 revealed that one of sixteen testing personnel had not signed an attestation in 2022 or 2023. There was no documentation that Employee #4 (as listed on the form CMS-209) had participated in proficiency testing in 2022 or 2023. C. In an interview, at 10:55 a.m. on 3/30/2023, laboratory Employee #2 (as listed on the form CMS-209) confirmed that Employee #4 routinely tests patient samples but has not participated in proficiency testing. She stated that employee #4 has been testing patients since June or July 2022.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

	Through review of the CMS 209 form, personnel records, and interview conducted on 3/30/2023 it was determined that the competency of the testing personnel was not assessed by the laboratory director on an annual basis. Findings follow: A) Review of personnel files for one of eight new testing personnel revealed that the initial and six month evaluation of the competency of the testing personnel (number four on the CMS 209 form) was not documented. B) Upon request, the laboratory could not provide initial and six competency evaluation of the testing personnel (number four on the CMS 209 form) dated 3/1/2023 subsequent to the evaluation identified above. C) In an interview on 3/30/2023 at 12:50 p.m. the testing personnel (number two on the CMS 209 form) said that testing personnel (number 4 on the CMS 209 form) had changed roles in May or June 2022 and no other competency evaluations were present and available.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory "CHEMISTRY QUALITY CONTROL POLICY", review of chemistry quality control (QC) Levey-Jennings Graphs for 2022 and 2023, lack of documentation, and interviews with staff, it was determined the laboratory failed to monitor over time the accuracy of chemistry test performance. Survey findings include: A. The CHEMISTRY QUALITY CONTROL POLICY states, "Shifts and trends will be monitored through the QC log and will be investigated further to determine the cause. Corrective action will be documented and saved in the LIS". It further states, "A QC trend or shift at DCMC (Dallas County Medical Center) lab will be when 4 consecutive controls values greater than are 1 SD (standard deviation) above or below the mean or 10 consecutive values above or below the mean regardless of their SD". B. A review of chemistry QC Levey-Jennings graphs for July 2022 revealed the following shifts as defined by the laboratory policy: NT-proBNP (B-type natriuretic peptide) Level 3 control was shifted above the expected mean all month (30 consecutive points); Troponin I Level 1 control was shifted below the expected mean for 22 consecutive points; Lipase Level 2 control was shifted above the mean all month (29 points); and Alkaline Phosphatase Level 3 control was shifted below the expected mean 26 consecutive points. C. A review of chemistry QC Levey-Jennings graphs for November 2022 revealed the following shifts as defined by the laboratory policy: Creatine Kinase Level 3 control was shifted below the expected mean all month (30 consecutive points); and Lipase Level 1 control was shifted below the mean 29 consecutive points. D. A review of chemistry QC Levey-Jennings graphs for February 2023 revealed the following shifts as defined by the laboratory policy: Calcium Level 1 control was shifted below the expected mean 12 consecutive points; Lipase Level 2 control was shifted below the expected mean for 22 consecutive

	points; Creatine Kinase Level 3 control was shifted below the mean all month (28 points); and Troponin I Level 1 control was shifted below the expected mean 27 consecutive points. E. Ten of ninety-eight Levey-Jennings graphs had shifts, as defined by the laboratory QC policy. The surveyor requested documentation of investigations for each of the shifts identified. None was provided. F. In an interview, at 11:05 a.m. on 3/29/2023, laboratory employee #2 (as listed on the CMS-209 form) stated there was no action documented for the shifts.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of bacteriology quality control documentation, lack of documentation, and interviews with staff, the laboratory failed to check each batch of microbiology media for sterility and ability to support growth. Survey findings include: A. A review of the bacteriology quality control documentation revealed there was no documentation of testing each lot or shipment of Blood Agar or McConkey Agar plates for sterility or ability to support growth. B. In an interview, at 2:43 p.m. on 3/29/2023, laboratory employee confirmed there was no documentation of testing each lot or shipment of Blood Agar or McConkey Agar for sterility or the ability to support growth of bacteria.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the blood gas laboratory's panic values policy, a review of patient ABG (arterial blood gas) reports, and interviews with laboratory staff, the laboratory failed to immediately alert the physician or charge nurse when panic values for ABGs are obtained for five of fifteen patients reviewed. Survey findings include: A. A review of the "ABG Panic Values" revealed the following: "The following is a list of panic values currently used: pH-----less than 7.35 or greater than 7.45; PCO2-----less than 35 or greater than 45; PO2-----less than 70 or greater than 90." The policy states, "When any of the panic values are present, the therapist will: Report the ABG results to the Charge Nurse and inform them of the Panic Value. Once you have done this - chart the date and time you reported it in clinical notes or write it on the ABG before scanning it in." B. Fifteen patient blood gas reports were reviewed. All blood gas reports had "Critical range" listed on the reports. The critical ranges listed on the reports were wider than the reportable ranges that the instrument were capable of and

	did not match the panic values listed in the policy titled "ABG Panic Values". Critical ranges listed on the patient reports were as follows: pH-----5.5 to 9.0; pCO2-----4.0 to 251.0; and pO2-----4.0 to 751.0. C. Review of patient reports revealed five of fifteen patient reports with results outside of panic values listed in the policy, failed to have documentation required by the policy (date and time the results were reported to the Charge Nurse). Patient #36255147 had blood gases performed on 2/26/23 at 01:57 and had a pH of 7.246 (panic range less than 7.35) and a pCO2 of 74 (panic range of greater than 45). Patient #12345678 had blood gases performed on 2/18/23 at 22:00 and had a pH of 6.865 (panic range less than 7.35), a pCO2 of 33.2 (panic less than 35), and pO2 of 123.6 (panic greater than 90). Patient #3253229 had blood gases performed on 1/11/23 at 17:56 and had a pCO2 of 58.1 (panic range of greater than 45) and a pO2 of 98.4 (panic greater than 90). Patient #3252822 had blood gases performed on 1/6/23 at 12:57 p.m. and had a pH of 7.166 (panic range less than 7.35), a pCO2 of 75.2 (panic range of greater than 45), and a pO2 of 372.5 (panic range greater than 90. Patient #3254524 had blood gases performed on 2/11/23 at 10:29 a.m. and had pCO2 of 23.5 (panic ranges less than 35) and a pO2 64.0 (panic range less than 70. D. In an interview at 10:15 a.m. on 3/30/23, laboratory employee #13 confirmed that documentation of notification of the charge nurse was not available for five of fifteen patients with panic values.